U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE REPUBLICANS

September 23, 2019

TO: Members, Committee on Energy and Commerce

FROM: Committee Minority Staff

RE: Hearing entitled **"**Sounding the Alarm: The Public Health Threats of E-Cigarettes."

The Subcommittee on Oversight and Investigations will hold a hearing on Wednesday, September 25, 2019, at 10:00 a.m. in 2123 Rayburn House Office Building, entitled "Sounding the Alarm: The Public Health Threats of E-Cigarettes."

I. WITNESSES

Panel One

- Anne Schuchat, MD (RADM, USPHS, RET), Principal Deputy Director, Centers for Disease Control and Prevention (CDC), U.S. Public Health Service (Retired); and
- Norman E. "Ned" Sharpless, MD, Acting Commissioner of Food and Drugs, U.S. Food and Drug Administration (FDA).

Panel Two

- Joneigh Khaldun, MD, MPH, Chief Deputy Director for Health and Chief Medical Executive, Michigan Department of Health and Human Services;
- Elizabeth Cuervo Tilson, MD, MPH, State Health Director and Chief Medical Officer, North Carolina Department of Health and Human Services;
- Monica Bharel, MD, MPH, Commissioner of the Massachusetts Department of Public Health; and
- Lee Norman, MD, Secretary, Kansas Department of Health and Environment.

II. BACKGROUND

a. E-cigarettes

Electronic cigarettes (e-cigarettes) produce an aerosol by heating a liquid that usually contains nicotine, flavorings, and other chemicals that help to make the aerosol users inhale into

their lungs.[1] E-cigarettes can also be used to deliver marijuana and other drugs. Users inhale this aerosol into their lungs, and bystanders can also breathe in this aerosol when the user exhales into the air. E-cigarettes come in different shapes and sizes and are known by different names such as "e-cigs," "e-hookahs," "mods," "vape pens," "vapes," "tank-systems," and "electronic nicotine delivery systems" (ENDS).[2] Some e-cigarettes look like regular cigarettes, cigars, or pipes, while others look like pens or USB sticks.[3]

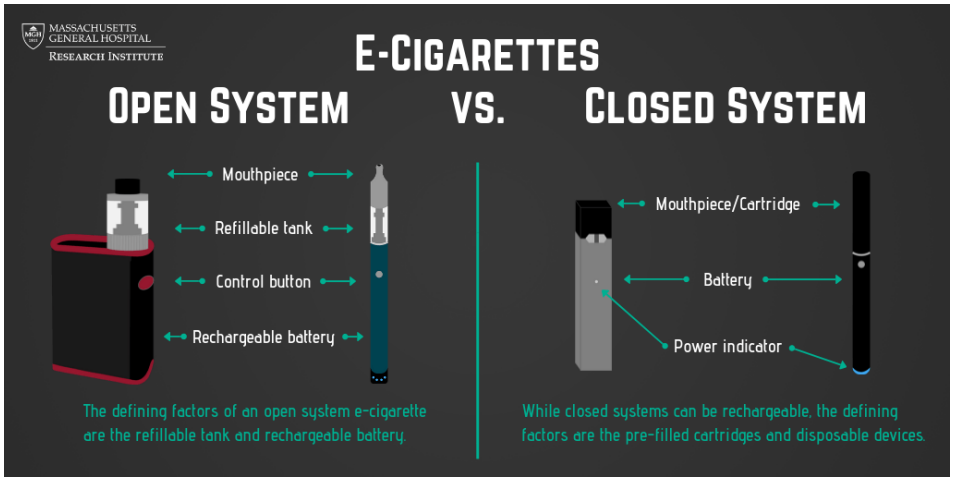
The aerosol from e-cigarettes can contain harmful and potentially harmful substances, including nicotine, and ultrafine particles that can be inhaled deep into the lungs, flavoring such as diacetyl, volatile organic compounds, cancer-causing chemicals, and heavy metals such as nickel, tin, and lead.[4] According to CDC, it is difficult for consumers to know what e-cigarette products contain. For example, some e-cigarettes marketed as containing zero percent nicotine have been found to have nicotine in them.[5]

According to CDC, "[e]-cigarettes have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products."[6] While some e-cigarette products can be less harmful than regular cigarettes, e-cigarettes are not harmless. Scientists are still learning about the long-term health effects from using e-cigarettes. What is known is that most e-cigarettes contain nicotine; e-cigarette aerosols can contain substances that harm the body; and e-cigarettes can cause unintended injuries—such as defective e-cigarette batteries causing fires and explosions, or acute nicotine exposure causing poisoning from swallowing, breathing, or absorbing e-cigarette liquid through skin or eyes.[7]

E-cigarettes can be a closed system or an open system. There are two types of closed system e-cigarettes. One has a pre-filled, disposable cartridge that attaches to rechargeable batteries (reusable closed system) and the other is a single-use product that cannot be recharged (disposable closed system). Open system e-cigarettes, which are largely sold at vape stores, can be filled with any e-liquid. According to researchers at the Mass General Research Institute, open system products "were often found to display inaccurate nicotine concentration levels, contain diacetyl…when labeled 'diacetyl-free,' and have lithium batteries that can occasionally

[1] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *About Electronic Cigarettes (E-Cigarettes), available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html#what-are-e-cigarettes (last accessed Sept. 23, 2019).
[2] *Id.*
[3] *Id.*
[4] U.S. Department of Health and Human Services, Public Health Service, Office of the Surgeon General, *E-cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* (2016), *available at* https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf.
[5] Goniewicz ML, Gupta R, Lee YH, et al. Nicotine levels in electronic cigarette refill solutions: a comparative analysis of products from the U.S., Korea, and Poland. Int J Drug Policy (2015 June ; 26(6):583–588), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4457636/pdf/nihms661813.pdf.
[6] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *Electronic Cigarettes What's The Bottom Line, available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/Electronic-Cigarettes-Infographic-p.pdf (last accessed on Sept. 22, 2019).
[7] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *About Electronic Cigarettes (E-Cigarettes), available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html#what-are-e-cigarettes (last accessed Sept. 23, 2019).

explode."[8] Most United States tobacco companies make closed system products with replaceable cartridges that have reliable, consistent, and accurate ingredient and nicotine labels.[9]



b. FDA Regulations

FDA oversees all pathways to market and distribute tobacco products in the United States legally. To introduce a new tobacco product to market, including ENDS, manufacturers must follow one of three pathways, otherwise the product may not be legally marketed in the United States. The manufacturer must file a premarket tobacco product application, demonstrate substantial equivalence, or request exemption from demonstrating substantial equivalence.[10]

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was signed into law on June 22, 2009.[11] The Tobacco Control Act gives FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products. Specifically, the Tobacco Control Act restricts tobacco marketing and sales to youth, requires smokeless tobacco product warning labels, ensures "modified risk" claims are supported by scientific evidence, requires disclosure of ingredients in tobacco products, and preserves state, local, and tribal authority.[12]

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[8] Mass General Research Institute Blog, Pediatric Research, *Not All E-Cigarettes are the Same: What Parents Need to Know* (Oct. 16, 2018), *available at* https://mghresearchinstitute.com/2018/10/16/e-cigarettes-and-adolescents-a-break-down-of-products-and-preferences/.
[9] *Id.*
[10] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *Market and Distribute a Tobacco Product*, *available at* https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product (last accessed Sept. 23, 2019).
[11] Pub. L. 111-31, Family Smoking Prevention and Tobacco Control and Federal Retirement Reform (June 22, 2009), *available at* https://www.govinfo.gov/content/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf.
[12] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *Family Smoking Prevention and Tobacco Control Act – An Overview*, *available at* https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview (last accessed Sept. 23, 2019).

The Tobacco Control Act provides FDA with the authority to regulate tobacco products. Cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco were immediately subject to the provisions of the Tobacco Control Act and FDA's regulatory authority. For other types of tobacco products, section 901(b) of the Food Drug and Cosmetic Act (21 U.S.C. 387a(b)) grants FDA the authority to deem those products subject to the law as well. Products made or derived from tobacco and intended for human consumption—including components and parts of tobacco products, whether or not they are themselves made or derived from tobacco—fall under the definition of tobacco product. Those products include a number of widely used and previously unregulated products, such as cigars, pipe tobacco, waterpipes (or hookah), dissolvable products, e-cigarettes and other electronic nicotine delivery systems (ENDS), collectively, the "newly deemed products."[13]

FDA finalized a rule effective August 8, 2016, which extended the agency's regulatory authority to all tobacco products, including electronic smoking devices, subject to the Food, Drug, and Cosmetic Act, including immediate restrictions on the sale and distribution of tobacco products. It immediately became illegal to sell e-cigarettes and other ENDS to anyone under age 18. Retailers became legally responsible for requiring age verification by photo ID for anyone under age 27 to purchase a tobacco product. All deemed products, including ENDS products, became subject to the premarket authorization requirements in the Tobacco Control Act, which meant that any ENDS product not on the market as of February 15, 2007, was a new tobacco product that must be authorized by FDA to be on the market.[14]

On July 27, 2017, FDA announced a four-year delay of the 2018 premarket tobacco application (PMTA) deadline for manufacturers of deemed tobacco products and extended the deadline to 2022. FDA announced it would seek input from the public on a variety of topics, including approaches to regulating youth-appealing flavors in e-cigarettes and cigars, and intended to issue Advance Notice of Proposed Rulemaking to seek public comment on the role that flavors, including menthol, in tobacco products play in attracting youth, and may play in helping some smokers switch to potentially less harmful forms of nicotine delivery. FDA also announced that it planned to finalize guidance on how it intended to review PMTAs for ENDS.[15]

In March 2018, the American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association Campaign for Tobacco-Free Kids and Truth Initiative filed a lawsuit against FDA demanding that FDA

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[13] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales, and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (Revised)** (Mar. 2019), *available at* https://www.fda.gov/media/97664/download.

[14] Ned Sharpless, MD, Acting Commissioner, U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *How FDA is Regulating E-Cigarettes, available at* https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulating-e-cigarettes (last access Sept. 23, 2019).

[15] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death* (July 27, 2017), *available at* https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.

reinstate the original deadline and begin enforcing the requirement for premarket review of all deemed products that were on the market as of August 8, 2016.[16]

In July 2019, the U.S. District Court for the Southern District of Maryland ruled to set aside FDA's guidance that gave e-cigarette companies until 2022 to file PMTAs and ordered that applications must be submitted to FDA no later than May 12, 2020, for products that were on the market as of August 6, 2016. The order provided a one-year period during which those products may remain on the market pending FDA review if the applications were filed timely, but also clarified FDA may enforce the premarket review provision prior to May 12, 2020, or during the review period.[17]

On September 20, 2019, FDA announced a proposed rule to establish requirements related to the basic content and format of PMTAs as part of the agency's continued commitment to its oversight of e-cigarettes and other tobacco products. The proposed rule, when finalized, would also establish the procedure by which FDA would review PMTAs and the requirements for manufacturers to maintain records establishing the legal marketing status of their tobacco products.

c. Youth E-Cigarette Use

Former FDA Commissioner Scott Gottlieb has described teen vaping as an epidemic, even though children younger than 18 are not not legally allowed to purchase vaping products.[18] Recent data shows a dramatic increase in use by youth. According to the National Youth Tobacco Survey, 27.5 percent of youths reported using e-cigarettes in 2019, compared with 20.8 percent in 2018. Three years ago, by comparison, 11.3 percent of youths reported using e-cigarettes.[19] The effects of nicotine on humans are not well-studied, although adolescents appear to be particularly vulnerable to it, with some evidence suggesting it can harm brain development. According to CDC, using nicotine in adolescence can harm the parts of the brain that control attention, learning, mood, and impulse control, and may also increase risk for future addiction to other drugs.[20] A January 2018 report by the National Academies of Science found substantial

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[16] American Academy of Pediatrics, *et al.*, v. Food and Drug Administration, *et al.*, Civil Action No. 8:18-cv-883-PWG (filed Mar. 27, 2018), *available at* https://www.tobaccofreekids.org/assets/content/press_office/2018/2018_03_27_filing.pdf.

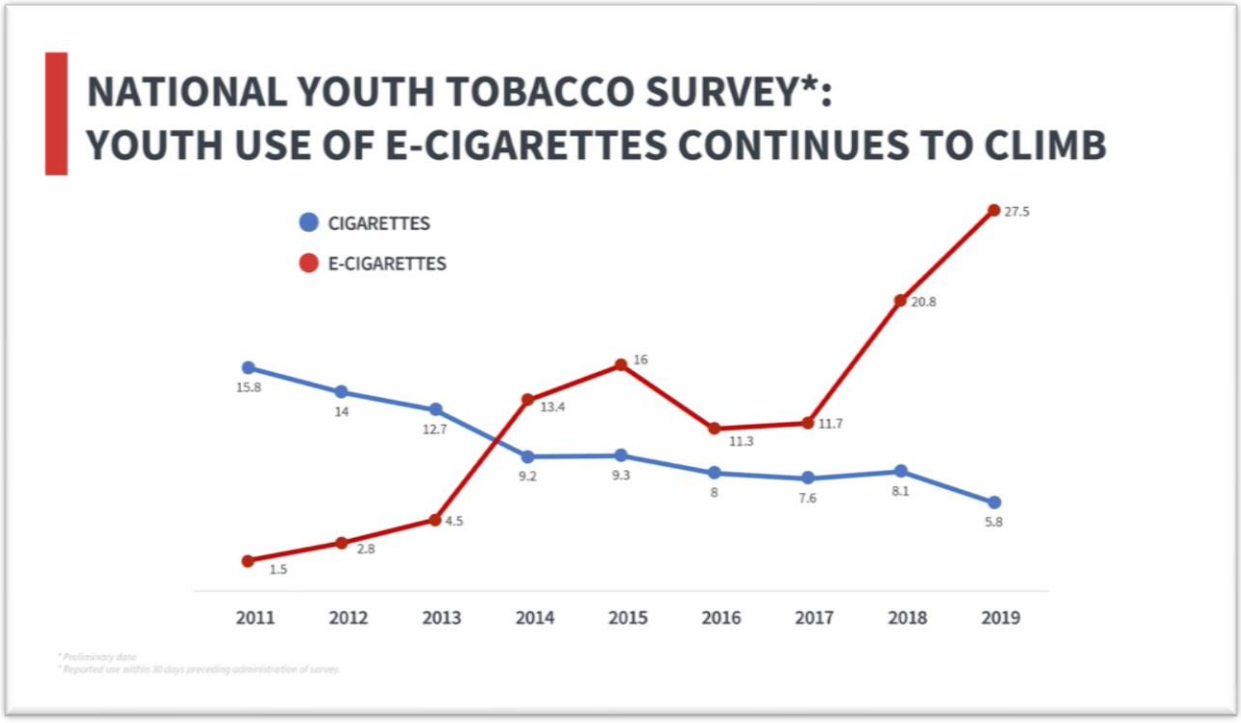
[17] American Academy of Pediatrics, *et al.*, v. Food and Drug Administration, *et al.*, Case 8:18-cv-00883-PWG, (filed July 12, 2019), *available at* https://www.tobaccofreekids.org/assets/content/press_office/2019/2019_07_12_fda_memo.pdf.

[18] *Id.*

[19] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019), *available at* https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non.

[20] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults, available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html#one (last accessed Sept. 23, 2019).

evidence that young vapers are more likely than non-vapers to try regular cigarettes.[21] While the trend of e-cigarette use has gone up over the past two years, youth use of cigarettes has continued to decline, as shown by the chart below.



As part of FDA's Comprehensive Plan for Tobacco and Nicotine Regulation, FDA has a Youth Tobacco Prevention Plan, which contains a series of efforts surrounding access, marketing, and education to stop youth use of tobacco products, especially e-cigarettes.[22] Specifically, FDA is conducting more than one million retail inspections; pursuing no tobacco sales orders to retail locations; taking actions on flavored tobacco products; addressing the epidemic of e-cigarette use; warning retailers for selling e-cigarettes to minors; eliminating enforcement discretion for products with youth appeal; protecting children from e-liquid dangers; requiring manufacturers to provide critical information; educating youth on the dangers of e-cigarette use; expanding "The Real Cost" campaign; and helping retailers comply with age restrictions.[23]

According to a survey involving approximately 25,000 adolescents published in an American Academy of Pediatrics abstract in October 2018, most of those who had used e-

[21] The National Academies of Sciences, Engineering, and Medicine, Consensus Study Report, *Public Health Consequences of E-Cigarettes* (Jan. 2018), *available at* https://www.nap.edu/resource/24952/012318ecigaretteConclusionsbyEvidence.pdf.
[22] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *FDA's Youth Tobacco Prevention Plan, available at* https://www.fda.gov/tobacco-products/youth-and-tobacco/fdas-youth-tobacco-prevention-plan (last accessed Sept. 23, 2019).
[23] *Id.*

cigarettes within the last 30 days reported starting out using closed systems then transitioned to using open e-cigarette systems. The majority of regular users prefer rechargeable systems. Researchers concluded the closed system e-cigarette serves as a starter product for users to graduate to using an open-system e-cigarette. The survey also indicated most adolescents who were regular e-cigarette users preferred rechargeable, refillable, open system e-cigarettes with flavored e-liquid, which were most often purchased at vape shops.[24]

On September 11, 2019, the Trump administration "announced that as part of its ongoing work to tackle the epidemic of youth e-cigarette use, the FDA intends to finalize a compliance policy in the coming weeks that would prioritize the agency's enforcement of the premarket authorization requirements for non-tobacco-flavored-e-cigarettes, including mint and menthol, clearing the market of unauthorized, non-tobacco-flavored-e-cigarette products."[25] In addition, multiple states, including Michigan and New York, as well as the District of Columbia, have proposed regulations on flavored e-cigarettes.[26] Michigan will effectively ban all flavored e-liquids except tobacco-flavored pods, and New York will only allow menthol and tobacco flavors.[27] The District of Columbia's proposal would ban all flavored e-cigarettes.[28]

d. Outbreak of Lung Illness Associated with Using E-cigarette Products

On August 30, 2019, CDC released a health advisory regarding severe pulmonary disease associated with using e-cigarette products.[29] The health advisory provided "1) background information on the forms of e-cigarette products, 2) information on the multistate outbreak of severe pulmonary disease associated with using e-cigarette products (devices, liquids, refill pods, and cartridges), and 3) clinical features of patients with severe pulmonary disease." The health advisory also provided "recommendations for clinicians, public health officials, and the public based on currently available information."[30]

As of August 30, 2019, the case classification criteria for a confirmed case includes: 1) using an e-cigarette ("vaping") or dabbing during the 90 days before symptom onset; 2)

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[24] Robert McMillen, Susanne Tanski, Karen Wilson, Jonathan D. Klein, Jonathan P. Winickoff, *Adolescent Use of Different E-cigarette Products*, Volume 142, Issue 4 (Oct. 2018), *available at* https://pediatrics.aappublications.org/content/142/4/e20180260.full

[25] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019), *available at* https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non.

[26] Terry Nguyen, *Flavored vapes are facing a ban. What does that mean for vapers?*, VOX (Sept. 18, 2019), *available at* https://www.vox.com/the-goods/2019/9/18/20872295/flavored-vape-ban-what-it-means-vapers.

[27] *Id.*

[28] Fennit Nirappil, *D.C. bills would block e-cigarette sales without a prescription, ban flavored products*, THE WASHINGTON POST (Sept. 17, 2019), *available at* https://www.washingtonpost.com/local/dc-politics/dc-bills-would-block-e-cigarette-sales-without-a-prescription-ban-flavored-products/2019/09/17/9526caba-d95e-11e9-a688-303693fb4b0b_story.html.

[29] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *Severe Pulmonary Disease Associated with Using E-Cigarette Products* (Aug. 30, 2019), *available at* https://emergency.cdc.gov/han/han00421.asp.

[30] *Id.*

pulmonary infiltrate, such as opacities on plain film chest radiograph or ground-glass opacities on chest computed tomography; 3) absence of pulmonary infection on initial workup: minimum criteria include negative respiratory viral panel, influenza polymerase chain reaction or rapid test if local epidemiology supports testing. All other clinical indicated respiratory infectious disease testing (e.g. urine antigen for *Streptococcus pneumoniae* and *Legionella*, sputum culture if productive cough, bronchoalveolar lavage culture if done, blood culture, human immunodeficiency virus-related opportunistic respiratory infections if appropriate must be negative; and 4) no evidence in medical record of alternative plausible diagnoses (e.g. cardiac, rheumatologic, or neoplastic process).[31]

As of August 30, 2019, the case classification criteria for a probable case includes: 1) using an e-cigarette ("vaping") or dabbing in 90 days before symptom onset; 2) pulmonary infiltrate, such as opacities on plain film chest radiograph or ground-glass opacities on chest computed tomography; 3) infection identified via culture or polymerase chain reaction, but clinical team believes this is not the sole cause of the underlying respiratory disease process **or** minimum criteria to rule out pulmonary infection not met (testing not performed) and clinical team believes this is not the sole cause of the underlying respiratory disease process; and 4) no evidence in medical record of alternative plausible diagnosis (e.g. cardiac, rheumatologic, or neoplastic process).[32]

As of September 19, 2019, 530 cases of lung injury associated with the use of e-cigarette or vaping products have been reported to CDC from 38 states and the U.S. Virgin Islands.[33] Seven deaths have been confirmed in California, Illinois, Indiana, Kansas, Minnesota, Missouri, and Oregon.[34] CDC has received complete sex and age data on 373 of 530 cases and nearly three fourths (72 percent) of cases are male, two thirds (76 percent) of cases are 18 to 34 years old and 16 percent of cases are under 18 years and 17 percent are 35 years or older.[35] According to CDC, "[a]ll patients have a reported history of e-cigarette product use, and no consistent evidence of an infectious case has been discovered. Therefore, the suspected cause is a chemical exposure."[36] In addition, most patients have reported a history of using e-cigarette products containing delta-9-tetrahydrocannabinol (THC), many patients have reported using THC and nicotine, and some have reported the use of e-cigarette products containing only nicotine.[37] However, to date, no consistent e-cigarette or vaping product, substance, or additive has been identified in all cases, nor has any one product or substance been conclusively linked to lung

[31] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Morbidity and Mortality Weekly Report (MMWR), *Severe Pulmonary Disease Associated with Electronic-Cigarette-Product Use – Interim Guidance* (Sept. 13, 2019), *available at* https://www.cdc.gov/mmwr/volumes/68/wr/mm6836e2.htm?s_cid=mm6836e2_e&deliveryName=USCDC_921-DM8485.
[32] *Id.*
[33] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping, available at* https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html (last accessed Sept. 23, 2019).
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] *Id.*

disease in patients.[38] According to Dr. Michael Siegel, a professor at Boston University School of Public Health, "[t]his outbreak does not appear to be associated with traditional legally-sold e-cigarettes, but with illicit and sometimes counterfeit THC vaping cartridges."[39]

e. Investigation of the Outbreak

CDC is coordinating a multistate investigation. Investigations in affected states are focused on describing exposures and the epidemiologic, clinical, laboratory, and behavioral characteristics of cases.[40] CDC has deployed to certain states with identified patients to assist with their state investigations and continues to work closely with affected states to characterize the exposures and the extent and progression of this illness. In addition, CDC has provided technical assistance to states and has issued a Clinical Action alert through its Clinician Outreach and Communication Activity network and has initiated data collection from states. On September 16, 2019, CDC announced that it had activated its Emergency Operations Center to enhance the inter-agency response to the current investigation into cases of lung injury associated with e-cigarette product use, or vaping.[41]

CDC is also working closely with FDA to facilitate collection of information regarding recent e-cigarette product use among patients and to provide technical assistance related to product samples associated with patients for chemical analysis of remaining substances or chemicals within the e-cigarettes. FDA is analyzing a collection of over 120 product samples provided by state public health officials for the presence of a broad range of chemicals, including nicotine, THC and other cannabinoids, cutting agents, additives, pesticides, opioids, poisons, heavy metals, and toxins.[42] FDA is focused on processing targeted product samples associated with clinical illness and will analyze samples if there is enough material to test. Public health

[38] *Id.*

[39] Erin Schumaker, *Most vaping deaths linked to THC devices, but experts still looking for root cause*, ABC NEWS (Sept. 19, 2019), *available at* https://abcnews.go.com/Health/vaping-deaths-linked-thc-devices-experts-root/story?id=65691076.

[40] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Morbidity and Mortality Weekly Report (MMWR), *Severe Pulmonary Disease Associated with Electronic-Cigarette-Product Use – Interim Guidance* (Sept. 13, 2019), *available at* https://www.cdc.gov/mmwr/volumes/68/wr/mm6836e2.htm?s_cid=mm6836e2_e&deliveryName=USCDC_921-DM8485.

[41] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, *Investigation of Lung Injury Associated with E-cigarette Product Use, or Vaping* (Sep. 16, 2019), *available at* https://www.cdc.gov/media/releases/2019/s0916-eoc-lung-injury.html.

[42] Emily Vaughn, *The Vaping Illness Outbreak: What We Know So Far*, NATIONAL PUBLIC RADIO (Sept. 18, 2019), *available at* https://www.npr.org/sections/health-shots/2019/09/18/760635457/the-vaping-illness-outbreak-what-we-know-so-far.

officials are working to determine whether the current outbreak is a new phenomenon or a case of raised awareness among medical providers and patients.

On September 19, 2019, FDA disclosed that the agency had opened a criminal probe into the cause of a mysterious vaping-related lung disease outbreak.[43] FDA's Office of Criminal Investigations (OCI) opened a probe "shortly after" people started falling ill.[44] An FDA official noted, "OCI has special investigative skills and the focus of their work is to identify what is making people sick, as well as a focus on the supply chain," he said. "Let me be clear, OCI is not pursuing any prosecutions associated with personal use of any controlled substances in these cases."[45]

[43] Angelica LaVito, *FDA opens criminal probe of vaping deaths as health officials search for cause*, CNBC (Sept. 19, 2019), *available at* https://www.cnbc.com/2019/09/19/fda-opens-criminal-probe-of-vaping-deaths-as-health-officials-search-for-cause.html.
[44] *Id.*
[45] *Id.*